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APPLICATION NO. **FILING DATE** FIRST NAMED INVENTOR ATTORNEY DOCKET NO. Ы 7295/43 09/781,655 02/12/01 MANDECKI **EXAMINER** HM12/1005 FREDMAN, J K. SHANNON MRKSICH, PH.D., ESQ. BRINKS HOFER GILSON & LIONE **ART UNIT** PAPER NUMBER P.O. BOX 10395 1655 CHICAGO IL 60610 **DATE MAILED:** 10/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



Office Action Summary

Application No. **09/781,655**

Applicant(s)

Mandecki

Examiner

Gary Jones

Art Unit **1655**

The MAILING DATE of this communication appe	ears on the cover sheet with the correspondence address
Period for Reply	
A SHORTENED STATUTORY PERIOD FOR REPLY IS STATE MAILING DATE OF THIS COMMUNICATION.	SET TO EXPIRE <u>three</u> MONTH(S) FROM
after SIX (6) MONTHS from the mailing date of this comm	7 CFR 1.136 (a). In no event, however, may a reply be timely filed unication. days, a reply within the statutory minimum of thirty (30) days will
be considered timely.	ory period will apply and will expire SIX (6) MONTHS from the mailing date of this
	II, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). r the mailing date of this communication, even if timely filed, may reduce any
Status	
1) Responsive to communication(s) filed on Sep 4,	, 2001
2a) ☐ This action is FINAL . 2b) ☒ This	action is non-final.
3) Since this application is in condition for allowan closed in accordance with the practice under Ex	ce except for formal matters, prosecution as to the merits is a parte Quayle, 1935 C.D. 11; 453 O.G. 213.
Disposition of Claims	
4) 🔀 Claim(s) <u>16-30</u>	is/are pending in the application.
4a) Of the above, claim(s) 27-30	is/are withdrawn from consideration.
5) Claim(s)	is/are allowed.
6) 💢 Claim(s) <u>16-26</u>	is/are rejected.
7) Claim(s)	is/are objected to.
8)	are subject to restriction and/or election requirement.
Application Papers	
9) \square The specification is objected to by the Examine	r.
10) The drawing(s) filed on is	are objected to by the Examiner.
11) The proposed drawing correction filed on	is: a) \square approved b) \square disapproved.
12) \square The oath or declaration is objected to by the Ex	aminer.
Priority under 35 U.S.C. § 119	
13) \square Acknowledgement is made of a claim for foreig	n priority under 35 U.S.C. § 119(a)-(d).
a) \square All b) \square Some* c) \square None of:	
1. \square Certified copies of the priority documents	have been received.
2. \square Certified copies of the priority documents	have been received in Application No
 3. Copies of the certified copies of the priorit application from the International E *See the attached detailed Office action for a list o 	
14) Acknowledgement is made of a claim for dome	
Attachment(s) 15) X Notice of References Cited (PTO-892)	18) Interview Summary (PTO-413) Paper No(s).
15 X Notice of Preferences Crea (P10-892) 16 Notice of Draftsperson's Patent Drawing Review (PTO-948)	18) Interview Summary (PTO-413) Paper No(s) 19) Notice of Informal Patent Application (PTO-152)
Information Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 16-26 in Paper No. 7 is acknowledged.

Sequence Rules

2. The current case fails to meet sequence rules because no new CRF has been submitted. However, the following paragraph, or language having the same effect, can be used to invoke the procedures of 37 C.F.R. 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

The computer readable form in this application, 09/781,655, is identical with that filed in application number 08/564,860, filed November 30, 1995. In accordance with 37 C.F.R. 1.821(e), please use the only computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary changes in application number and filing date for the computer readable form that will be used for the instant application.

A paper copy of the Sequence Listing should be attached to the form for entry into the originally filed specification of the instant application.

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Claim Rejections - 35 USC § 112

3. Claims 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what step (c) is in claim 16, since the claim progress from step (b) to step (d) without any elucidation of step (c).

Double Patenting

4. Claims 16-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,051,377 in view of either Zavracky et al (U.S. Patent 4,989,934) or Nova et al (U.S. Patent 5,751,629).

Claims 1-19 of U.S. Patent No. 6,051,377 teach a method of detecting a target nucleic acid sequence in a sample, comprising the steps of: (a) providing a solid phase comprising particles having transponders, the transponders having memory elements, the particles having a nucleic acid probe attached to a surface of the solid phase particles, the probe having a sequence complementary to a target sequence, the transponders having an index number encoded in the memory element; (b) contacting the solid phase with a sample to form a sample mixture; (c) increasing the amount of the target nucleic acid subjected to analysis by PCR amplification, using at least one oligonucleotide primer which is not immobilized on the solid phase, said PCR amplification comprising at least one cycle of: (1) denaturation of nucleic acids in the sample mixture; (2) hybridization of nucleic acids in the sample mixture; (3) chain extension with DNA

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polymerase; (d) analyzing the solid phase to detect the presence of a label indicative of binding of the target nucleic acid; and (e) decoding the data encoded on transponders using the dedicated read/write scanner to identify the class of transponders to which analytes are bound.

Claims 1-19 of U.S. Patent No. 6,051,377 does not teach that the transponder is a monolithic integrated circuit.

Zavracky teaches an monolithic integrated transponder device (abstract).

Nova teaches a monolithic integrated transponder device (which is simply a device on a single substrate) (column 7, lines 6-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the use of monolithic integrated circuits with the detection method of claims 1-19 of U.S. Patent No. 6,051,377 since Nova states "The preferred miniture recording device for usin in the combinations herein is a single substrate (column 7, lines 7-8)"., thus expressly motivating selection of single substrate devices. Motivation is also provided by Zavracky, who states "As these systems become sufficiently complex, the use of optoelectronic integrated circuites (OEIC) is becoming increasingly attractive for cost and performance reasons (column 1, lines 20-23)". An ordinary practitioner would have been motivated to use monolithic integrated circuits in the method of claims 1-19 of U.S. Patent No. 6,051,377 for the express motivation of Nova that this is a preferred embodiment and for the express motivations of Zavracky who notes that these integrated circuits are preferred for cost and performance reasons.

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5. Claims 16-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,001,571 in view of either Zavracky et al (U.S. Patent 4,989,934) or Nova et al (U.S. Patent 5,751,629).

Claims 1-12 of U.S. Patent No. 6,001,571 teach a method of detecting a target nucleic acid sequence in a sample, comprising the steps of: (a) providing a solid phase comprising particles having transponders, the transponders having memory elements, the particles having a nucleic acid probe attached to a surface of the solid phase particles, the probe having a sequence complementary to a target sequence, the transponders having an index number encoded in the memory element; (b) contacting the solid phase with a sample to form a sample mixture; (c) denaturation of nucleic acids in the sample mixture; (d) hybridization of nucleic acids in the sample mixture, (e) analyzing the solid phase to detect the presence of a label indicative of binding of the target nucleic acid; and (f) decoding the data encoded on transponders using the dedicated read/write scanner to identify the class of transponders to which analytes are bound.

Claims 1-12 of U.S. Patent No. 6,001,571 does not teach that the transponder is a monolithic integrated circuit.

Zavracky teaches an monolithic integrated transponder device (abstract).

Nova teaches a monolithic integrated transponder device (which is simply a device on a single substrate) (column 7, lines 6-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the use of monolithic integrated circuits with the detection

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method of claims 1-12 of U.S. Patent No. 6,001,571 since Nova states "The preferred miniture recording device for usin in the combinations herein is a single substrate (column 7, lines 7-8)"., thus expressly motivating selection of single substrate devices. Motivation is also provided by Zavracky, who states "As these systems become sufficiently complex, the use of optoelectronic integrated circuites (OEIC) is becoming increasingly attractive for cost and performance reasons (column 1, lines 20-23)". An ordinary practitioner would have been motivated to use monolithic integrated circuits in the method of claims 1-12 of U.S. Patent No. 6,001,571 for the express motivation of Nova that this is a preferred embodiment and for the express motivations of Zavracky who notes that these integrated circuits are preferred for cost and performance reasons.

6. Claims 16-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,736,332 in view of either Zavracky et al (U.S. Patent 4,989,934) or Nova et al (U.S. Patent 5,751,629).

Claims 1-11 of U.S. Patent No. 5,736,332 teach a method of determining the sequence of a target nucleic acid sequence in a sample, comprising the steps of: (a) providing a solid phase comprising particles having transponders, the particles having an oligonucleotide probe attached to a surface of the solid phase particles, the transponders having memory elements and an index number indicating sequence of the probe encoded on the transponders; (c) contacting the solid phase with a sample to form a sample mixture; (d) denaturing nucleic acids in the sample mixture; (e) hybridizing the nucleic acids in the sample mixture, whereby target nucleic acid sequences hybridize to complementary probes; (f) analyzing the solid phase to detect the presence of a label

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indicative of binding target nucleic acid to probes; (g) decoding the data encoded on transponders using the dedicated read/write scanner to identify the sequence of the probes to which target nucleic acids are bound.

Claims 1-11 of U.S. Patent No. 5,736,332 does not teach that the transponder is a monolithic integrated circuit.

Zavracky teaches an monolithic integrated transponder device (abstract).

Nova teaches a monolithic integrated transponder device (which is simply a device on a single substrate) (column 7, lines 6-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the use of monolithic integrated circuits with the detection method of claims 1-11 of U.S. Patent No. 5,736,332 since Nova states "The preferred miniture recording device for usin in the combinations herein is a single substrate (column 7, lines 7-8)"., thus expressly motivating selection of single substrate devices. Motivation is also provided by Zavracky, who states "As these systems become sufficiently complex, the use of optoelectronic integrated circuites (OEIC) is becoming increasingly attractive for cost and performance reasons (column 1, lines 20-23)". An ordinary practitioner would have been motivated to use monolithic integrated circuits in the method of claims 1-11 of U.S. Patent No. 5,736,332 for the express motivation of Nova that this is a preferred embodiment and for the express motivations of Zavracky who notes that these integrated circuits are preferred for cost and performance reasons.

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Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 16-22 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al (JP 04148700 A2) in view of Nova et al (U.S. Patent 5,751,629).

Nagai teaches a method of detecting a target nucleic acid comprising the steps: a) providing a solid phase particle, b) contacting said solid phase particle with said sample, d) denaturing nucleic acids in the sample mixture, e) hybriding the nucleic acid in the mixture such that the target will hybridize with the oligonucleotide bound to the solid phase particle, f) detecting the hybridized complex (abstract and entire patent, especially page 748, column 2 and page 749, column 1). Nagai further teaches the use of a fluorescent labels covalently linked to the nucleic acids and a flow cytometer (abstract, page 748, column 1, and figures 1 and 2).

Nagai does not teach the use of a monolithic integrated transponder photocell device as the solid phase particle for detection using a hardware connected antenna in the flow cytometer and the examiner is unsure of whether Nagai teaches adjustment of the size of the flow cytometer for the particles.

Nova teaches multiplex detection of biopolymer interactions using solid phase particles which are monolithic integrated transponder devices (column 23-26). Nova expressly teaches

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detection of nucleic acids by immobilization onto the solid particles (columns 13 and 37). Nova teaches a scanner device which comprises (a) a chamber for solid phase particles with transponders which chamber is adjusted to allow for the flow of the solid phase particles (column 28, lines 42-67), (b) a fluorometer (column 28, line 63 to column 29, line 49), (c) an antenna for receiver a radio frequency signal (column 28, lines 56-62). Nova further teaches a flow system for solid phase particles (column 28, lines 42-55). Nova further teaches a laser in the device (column 28, line 65). Nova further teaches hardware to decode the signal (columns 29 and 30), as well as magneto-optical materials and optical discs (column 30). Nova further teaches the use of photocells in the integrated device (columns 26 and 27).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Nagai with the use of transponders as taught by Nova since Nova states "These combinations are particularly advantageous for use in multianalyte analyses (column 1, lines 37-40)". An ordinary practitioner would have been motivated to combine the flow cytometric method of Nagai with the combined flow cytometric and transponder method of Nova for the express benefit of ease of multianalyte analyses, the simpler recording and identification of data points and the greater control provided by the additional tracking using the radiofrequency tags (see column 1, lines 60-63).

9. Claims 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al (JP 04148700 A2) in view of Nova et al (U.S. Patent 5,751,629) and further in view of Kobayashi et al (Mol. Cell. Probes (June 1995) 9:175-182).

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Nagai in view of Nova teach the limitations of claims 16-22 and 25-30 as discussed above.

Nagai in view of Nova do not teach single nucleotide extension using fluorescent dideoxynucleotide terminators.

Kobayashi teaches single nucleotide extension using fluorescent dideoxynucleotide terminators (abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Nagai in view of Nova with the method of Kobayashi since Kobayashi states "In conclusion, mutation detection employing an automated, fluorescence based multiplex minisequencing approach offers many advantages over current approaches. (Page 180, column 2)". An ordinary practitioner would be motivated to utilize the flow cytometric method of Nagai in view of Nova with the fluorescent minisequencing approach of Kobayashi for the expected benefits of a more cost effective, rapid and high volume assay for DNA based screening for known mutations in a clinical laboratory setting.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655